

### **REMARKS**

Claims 6 and 32-111 have been canceled previously without prejudice. Accordingly, claims 1-5, 7-31, 112-118 are pending and presented for examination.

No new matter is added by the present Amendment. Applicant specifically traverses the Examiner's withdrawal of previously submitted claims 113-118 and addresses this issue in the remarks below. Applicant respectfully reserves the right to pursue the subject matter of the canceled or amended claims in a related application. The rejection levied in the Office Action is addressed below.

#### **Interview**

Applicant thanks the Examiner for granting a telephonic interview on May 14, 2010. In that interview, the withdrawal of claims and the cited art were discussed. Specifically, Applicant traversed the Examiner's withdrawal of previously added claims 113-118 because it is not a fact that those claims are drawn to a non-elected invention as asserted in the Office Action. Applicant also explained to the Examiner that the cited reference, U.S. Patent 2,882,249 ("Posnansky") does not teach "a polyurethane matrix formed by a reaction of polyisocyanate with a hydroxylated biomolecule" such as a fatty acid, as recited in the claims. Applicant further offered an analogy drawn to a dipeptide in order to help the Examiner to see *structural limitations* defined by this claim language.

Applicant respectfully reiterates and expands arguments on these points in the following remarks.

#### **Election/Restrictions**

Claims 113-118 are withdrawn by the Examiner from consideration as being directed to a non-elected invention in the Office Action. The Examiner seems to base her conclusion on that "Applicant was presented with a restriction in the office action date June 26, 2007 wherein the optionally hydroxylated biomolecules selected from polysaccharides, lipids or phospholipids were not elected (group II invention)" (see, page 2 in the Office Action). Applicant respectfully disagrees .

In the Restriction Requirement mailed June 26, 2007 (the “Restriction Requirement”), for the present application, the Examiner restricted claims into the following six (6) groups:

- I. Claims 1-31, drawn to a biodegradable polyurethane composition comprising a polyurethane matrix formed by reaction of a polyisocyanate with an optionally hydroxylated biomolecule, and a reinforcement embedded in the matrix selected from bone and bone substitutes, classified in class 623, subclass 23.51.
- II. Claims 32-62, drawn to a biodegradable polyurethane composition comprising a polyurethane matrix formed by reaction of a polyisocyanate with an optionally hydroxylated biomolecule wherein the optionally hydroxylated biomolecules comprises polysaccharides and lipids or phospholipids, classified in class 623, subclass 23.75.
- III. Claims 63-79, drawn to a polyurethane, formed by a reaction of a polyisocyanate with a biomolecule to form a nonresorbable polyurethane polymer, classified in class 623, subclass 23.58.
- IV. Claims 80-89, drawn to a method of making a polyurethane composite having particles of reinforcement embedded therein selected from bone and bone substitutes, classified in class 525, subclass 63.
- V. Claims 90-99, drawn to a method of making a polyurethane composite wherein the mixture of optionally hydroxylated biomolecules comprise polysaccharides, lipids and phospholipids, classified in class 525, subclass 54.2.
- VI. Claims 101-111, drawn to a method of making a polyurethane to form a nonresorbable polyurethane polymer wherein the biomolecule comprises a polysaccharide, classified in class 525, subclass 54.24.

Responsive to the Restriction Requirement, Applicant elected on July 26, 2007, Group I (claims 1-31), drawn to a biodegradable polyurethane composition comprising a polyurethane matrix formed by reaction of a polyisocyanate with an optionally hydroxylated biomolecule, and a reinforcement embedded in the matrix selected from bone and bone substitutes. On September

26, 2007, a non-final Office Action was mailed, in which Applicant's election of Group I was acknowledged and claims 1-31 were presented for examination.

In the last Response dated December 2, 2009, Applicant added new dependent claims 113-118. The subject matter of these claims are within the scope of originally-filed, and now-canceled dependent claim 6. Claim 6 was elected within Group I and has been examined by the Examiner previously. Therefore, Applicant respectfully submits that the newly added dependent claims 113-118 read on the elected invention, Group I as set forth in the Restriction Requirement.

Furthermore, the Examiner seems to have taken the position that these claims read on Group II invention. This is incorrect. Group I invention as set forth in the Restriction Requirement is directed to a polyurethane composition comprising a polyurethane matrix formed by a polyisocyanate with an optionally hydroxylated biomolecule, and a reinforcement embedded in the matrix, whereas Group II invention is directed to a polyurethane formed by a polyisocyanate with an optionally hydroxylated biomolecule as well, but specifies that the optionally hydroxylated biomolecules comprises polysaccharides and lipids or phospholipids. Newly added claims 113-118 depend from claim 1 still reciting the features of a reinforcement embedded in the polyurethane matrix, which are distinct from Group II invention according to the Restriction Requirement.

Therefore, dependent claims 113-118 belong to Group I invention, the originally elected group. Applicant respectfully requests that the withdrawal of claims 113-118 be removed.

#### Claim Rejections – 35 U.S.C. § 103

Claims 1-5, 7-31 and 112 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 2,882,249 ("Posnansky"); U.S. Patent 6,123,731 ("Boyce"); and Bruin *et al.*, *Makromol. Chem. Rapid Commun.* 9:589-594, 1988 ("Bruin").

The Examiner states that Posnansky teaches "the formation of polyurethanes by the reaction between a polyisocyanate such as diisocyanate and hydroxy containing monobasic fatty acids" (see, page 4 in the Office Action). Boyce is cited for teaching the use of bone or other substances combined with a polymer in osteoimplants. The Examiner further relies on Bruin for

providing teachings of properties of polyurethane such as mechanical strength and asserts that the claims reciting these properties stand rejected “based on ‘inherency’ under 35 U.S.C. § 102, on ‘*prima facie* obviousness’ under 35 U.S.C. § 103, jointly or alternatively” (see, page 6 on the Office Action). Applicant strongly traverses the rejection.

As discussed in the interview with the Examiner, the present claims recite a biodegradable polyurethane composite comprising a polyurethane matrix and a reinforcement embedded in the matrix. The claims further specify that the polyurethane is formed by reaction of: (A) a polyisocyanate; and (B) a particular type of biomolecules (e.g., a hydroxylated biomolecule selected from phospholipid or a modified form of the phospholipid, a fatty acid, a cholesterol or a modified form of the cholesterol, a polysaccharide or a modified form of the polysaccharide, a starch or a modified form of the starch, or any combination of the above).

The Examiner has taken the position that the language “formed by” is a process phrase that does not place any boundaries in the structure of the reacted polyurethane. The Examiner is mistaken.

Applicant has offered an analogy that a claim reacting a dipeptide “formed by” linkage of alanine to threonine would produce a dipeptide of a particular structure independent of a process by which it was produced. Same is true of the present “formed by” claim language. Specific identities of components reacted to form polyurethane determine the specific structure of the formed polyurethane. Those of ordinary skill in the art would appreciate that the amide linkage between alanine and threonine in the formed dipeptide corresponds to a urethane linkage between the polyisocyanate and the hydroxylated biomolecule in the formed polyurethane as recited in the claims. Both reactions and linkages are so well known in the art. An ordinary artisan in the art reading that a dipeptide “formed by” A and B, for simplification, would be able to determine the specific structure of the formed dipeptide, A-B. Same applies to a polyurethane “formed by” components A and B (i.e., a polyisocyanate and a hydroxylated biomolecule). The artisan would also be able to determine the structural unit of the formed polymer, that is, A-B.

Applicant acknowledges that the proposed analogy recites a single species of dipeptide (Ala-Thr), whereas the present claims recite a class of polyurethane. However, the point of the analogy still holds. For example, a claim to a dipeptide, which is formed by linkage of an

hydroxylated amino acid with an alkyl-side-chained amino acid would also describe a set of dipeptides by structure, and not by methods of making.

Furthermore, the cited art is not relevant to the present claims. Posnansky teaches the reaction of non-linear *polyacidesters* polymerized from hydroxy-containing fatty acids, with polyisocyanates to form plastic materials. Reaction of the non-linear polyacid polymers with a polyisocyanate leads to the formation of urethane linkages between the polyacid polymer and the polyisocyanate. More specifically, Posnansky emphasizes that “in order to form the materials which are to be treated with polyisocyanate, several of the hydroxy-containing molecules of the fatty acid **must** be combined into a non-linear ester or other form of non-linear polyacid polymer” (see, col. 3, lines 9-13). Posnansky also explicitly teaches that “the **initial step** in the preparation of these new products is to manufacture a non-linear polymer from a long chain hydroxy-containing monobasic fatty acid” (see, col. 3, lines 44-47), and then the relatively expensive polyisocyanate are used in crosslinking the polyacidester to form “even larger molecules” (see, col. 1, lines 56-64).

Independent claim 1, as amended, recites reacting a polyisocyanate (component A) with a biomolecules, for example, a fatty acid (component B). The structural unit of the polyurethane formed as described in the claims is “A-B” as discussed above. By contrast, Posnansky teaches reacting a polyisocyanate (component A) with a *polyacidester* (component C). C is generated by polymerizing a long chain hydroxy-containing monobasic fatty acid (i.e., component B),

resulting in  $\text{---}\text{B}\text{---}_n$ . The structural unit of the polyurethane formed in Posnansky is “A-C”, which is clearly different from “A-B”. Posnansky thus cannot anticipate the claimed invention.

By expressly teaching the use of a *polyacidester* (component C) rather than a fatty acid (component B), Posnansky indeed leads a person of ordinary skill in a direction divergent from the path that was taken by the Applicant (*See In re Gurley*, 27 F.3d 551, (Fed. Cir. 1994); *see also* *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877 (Fed. Cir. 1998)), and therefore *teaches away* from the claimed polyurethane composition (i.e., “A-B”).

Still further, as the Examiner admits, Posnansky does not teach a reinforcement embedded in the matrix as claimed. The Examiner cites Boyce for teaching the use of bone

combined with a polymer in osteoimplants. Boyce teaches an osteoimplant with chemical linkages between the surface-exposed collagen of adjacent partially demineralized bone elements with a nonbioasorbable material. Applicant reiterates the arguments made in the previous Response submitted on December 2, 2009, Boyce does not explicitly teach a polyurethane prepared by reacting a biomolecule with a polyisocyanate as claimed but rather discloses polyurethanes generally in a long list of possible polymers. The generic disclosure cited by the Examiner in column 4 certainly does not provide a teaching or even a suggestion for the use of a polyurethane made from a biomolecule. Even assuming for the moment that Posnansky could be combined with Boyce, the two references could not arrive at the claimed invention because the combined teachings at least would not describe a polyurethane formed by a polyisocyanate and a hydroxylated biomolecule as recited in the claims.

Bruin does nothing to remedy the deficiencies as noted above. Bruin discloses reacting starshaped or linear polyester *prepolymers* (not a biomolecule) with diisocyanates to form poly(ester-urethane) networks. Bruin, alone or taken together with Posnansky and Boyce even if all could be combined, still fails to disclose the use of a polyurethane made from a *hydroxylated biomolecule* reacting with a polyisocyanate as claimed. For at least this reason, the Examiner has not made a *prima facie* case of obviousness because all limitations of the claimed invention are not taught by the asserted combination of references.

With respect to the rejection based on inherency under 35 U.S.C. § 102, the Examiner is reminded that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Nowhere in Bruin is it taught that any reinforcement is embedded in the polyurethane matrix. In fact, Bruin merely reports tensile strength of the polyurethane networks formed by a *prepolymer* reacted with a polyisocyanate, without any reinforcement components. Applicant respectfully submits that the compositions described in the cited art are not even close to the claimed invention, and the properties recited in the present claims such as wet compressive strength are not necessarily present in Bruin's polyurethane. Indeed, those of ordinary skill in the art would appreciate that a polyurethane in which a reinforcement is embedded would have mechanical strength different (e.g., improved)

from that of the polyurethane disclosed in Bruin. Therefore, inherency has not been established by the Examiner either.

In light of the above remarks, Applicant respectfully requests that the rejection be withdrawn.

### Conclusion

For at least the reasons set forth above, each of the rejections in this case should be removed and the application should proceed to allowance. If, at any time, it appears that a phone discussion would be helpful, the undersigned would greatly appreciate the opportunity to discuss such issues at the Examiner's convenience. The undersigned can be contacted at (617) 248-5175.

It is believed that all fees due with this response are being submitted herewith. To the extent that there are any discrepancies between what Applicant has paid with the filing and/or prosecution of the present Application and what the USPTO believes is owed, please apply any charges or credits to deposit account 03-1721, referencing Attorney Docket No. 2004367-0034. Applicant respectfully requests that a Notice be issued explaining any such discrepancy.

Respectfully submitted,

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